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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/913,056	10/22/1997	NAKAYUKI YAMAMOTO	KP-8240	5317

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EXAMINER	
WEBMAN, EDWARD J	

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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 26

Application Number: 08/913,056
Filing Date: October 22, 1997
Appellant(s): YAMAMOTO ET AL.

A. J. Patch
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/28/03.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Applicants state that the claims are not grouped for appeal.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,645,854	MASIZ	7-1997
5,750,141	ROBERTS	5-1998
5,149,537	AZRIA	9-1992

PHARMACEUTICAL RESEARCH	KISSEL	1992
3-5427	JAPAN	1-1991
215697	EPA	3-1987
94157	EPA	11-1983
4557934	COOPER	12-1985
115627	EPA	8-1984
4882359	NAKAGAWA	11-1989
5011824	MASADA	4-1991
5120546	HANSEN	6-1992
5240995	GYORI	8-1993
5302172	SAGE, JR	4-1994
5167616	HAAK	12-1992

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-27 are rejected under 35 U.S.C. 103. This rejection is set forth in prior Office Action, Paper No. 23.

Majeti is withdrawn from the rejection.

Claims 1-3, 18, 19, 21-27 are rejected under 35 U.S.C. 103. This rejection is set forth in prior Office Action, Paper No. 23.

Claims 3-17, 21 are rejected under 35 U.S.C. 112. This rejection is set forth in prior Office Action, Paper No. 23.

(11) Response to Argument

Applicants argue that Roberts et al does not disclose physiologically active peptides. However, the role of the vasodilator in Masiz is independent of the active agent (column 2 line 61, column 3 line 3).

Thus, applicants argument that Hansen et al do not specifically match the cited vasodilator with the cited peptide is rendered irrelevant in view of this observation.

Applicants argue that the Masiz vehicle does not teach transmucosal administration because the vehicle does not "stay together" in view of the dissolution of the gum binding the three elements of the vehicle. However, applicants implication that the vehicle does not "stay together" long enough for transmucosal delivery is mere opinion. Applicants argue that they claim only Nasal or recital mucosa. However, Masiz also teaches exposure of his device to mucoid secretions other than saliva (column 5 line 29) indicating placement of the device in ~~location~~ loci other than the mouth where such secretions are present.

Applicants also rebut the argument that applicants limitation to transmucosal delivery is an intended use by arguing that such a limitation renders the obvious combination improper. However, this rebuttal assumes that the limitation is not an intended use. On the contrary, the language "for" is clearly indicative of such a use.

Regarding the second rejection, applicants argue Hindsite. However, motivation to combine is provided. Applicants find the combination incomprehensible. However, all three teach iontophoretic delivery.

Applicants also argue that neither of the secondary references teach mucosal delivery. However, the primary reference teach the equivalence of delivery to the skin

or a mucosal membrane. Alternatively, as for the first rejection, it is argued that applicants' limitation as to locus of delivery is merely an intended use.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Webman/tgd
September 23, 2003

Conferees
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